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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,623	08/27/2001	Xianxhang Yu	035879-0125	2349

22428 7590 02/07/2007
FOLEY AND LARDNER LLP
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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/938,623

Applicant(s)

YU ET AL.

Examiner

Karen A. Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-11, 13-32, 34-50 and 52-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6, 8-11, 13-27, 29-32, 34-45, 47-50, 52-60 is/are rejected.
- 7) ☐ Claim(s) 7, 28 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

After review and reconsideration, the finality of the Office action of July 18, 2006, is withdrawn.

Claims 1-11, 13-32, 34-50 and 52-60 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11, 32 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claim are reliant on the identity of a neo-vascular targeting sequence of an anti-fibronectin ED-B antibody. The claim thus encompass the paratope of an ED-B antibody. The claims are not limited to single chain antibodies, or linear paratopes and encompass topographic paratopes within anti-fibronectin ED-B antibodies. It is recognized in the art that the ED-B antibody binds to the ED-B domain of fibronectin, and this domain is expressed within the neovasculature. A description of the ED-B domain does not provide for the description of an antibody which binds thereto because it is not possible to anticipate the sequence of an antibody paratope given a given antigen to which said antibody binds. The specification does not describe a single neo-vasculature targeting sequence of an anti-ED-B antibody. One of skill in the art would reasonable conclude that applicant was not in possession of the targeting molecule which is a neo-vascular targeting sequence of an anti-fibronectin EB-D antibody. .

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 8, 13, 14-24, 26, 29, 34-42, 44, 47, 52-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Rivett et al (WO 97/33908, IDS reference).

Claim 1 is drawn to a procytoxin comprising a cytotoxic peptide bound to an inactivator via a peptide bond, wherein said cytotoxic peptide is a pore-forming cytolytic peptide that comprises an amphipathic alpha-helical structure, and wherein said peptide bond is susceptible to cleavage by a targeting specific protease.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 6, 8-10, 13-27, 29-31, 34-45, 47-49 and 52-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivett et al (WO 97/33908) in view of Glazier (U.S. 2003/0138432, cited in a previous Office action).

Glazier teaches the targeting specific proteases of PSA (paragraphs 1329, 1354-1356), PSMA (paragraphs 710, 1015, 1019), matrix metalloproteinases (paragraphs 0698, 699 and 727-

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732). Glazier teaches the targeting of tumor neovasculature for drug delivery (paragraphs 958, 1291) and the use of the "RGD" targeting sequence (paragraphs 954-955). It would have been prima facie obvious at the time the invention was made to direct the procytotoxin of the invention to a tumor cell or the neovasculature surrounding a tumor cell to allow for more specificity of treatment. One of skill in the art would have been motivated to do so by the teachings of Glazier.

Claims 1-3, 5, 8, 9, 11, 13-24, 26, 29, 30, 32, 34-42, 44, 47, 48, 50, and 52-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivett et al (WO 97/33908) in view of Neri et al (WO 97/45544).

Neri et al teach the in vivo targeting of tumor vasculature comprising the administration of recombinant anti-fibronectin ED-B antibodies (page 1, lines 4-9, page 22-27, examples 1 and 2 and page 35, example 3). Neri et al teach that targeting of the tumor vasculature is an indirect form of tumor therapy resulting in the damaging of the blood vessels supplying the tumor (page 16, lines 13-26).

It would have been prima facie obvious to use the targeting sequence of the recombinant anti-fibronectin taught by Neri et al in the method of Rivett et al. One of skill in the art would have been motivated to do so by the teachings of Neri et al

Claims 7, 28 and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

2/3/2007



KAREN CANELLA, Ph.D.
PATENT EXAMINER